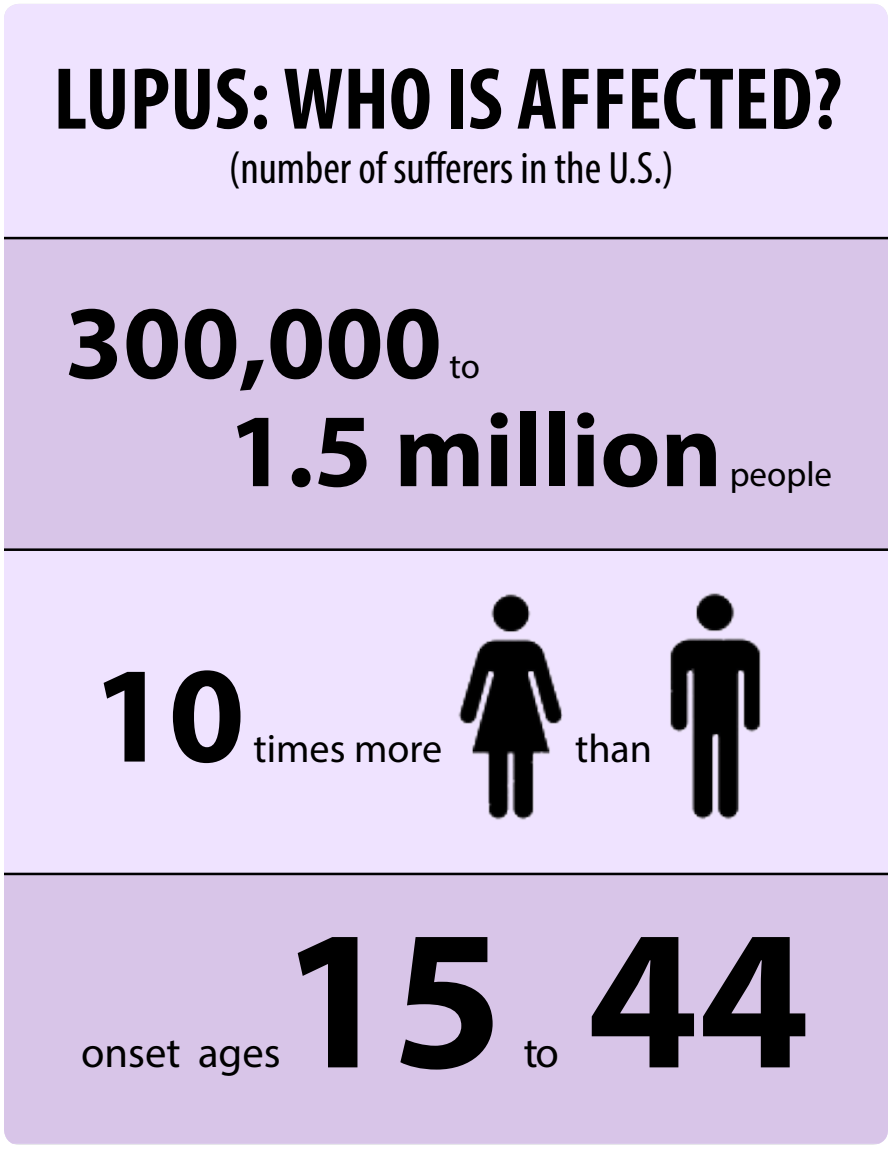
Lupus Therapies Continue to Evolve

It can be a difficult disease to diagnose and a difficult disease to treat. It's called lupus, and as many as 24,000 people in the United States are diagnosed with the disease each year.

May is National Lupus Awareness month, a time to think about lupus and the challenges it presents patients, researchers and health care professionals alike. Scientists today are working on many fronts to understand the genetic underpinnings of the disease and to develop new and more targeted therapies to treat it.

What is Lupus?

Lupus is a disease that can damage many parts of the body, including the joints, skin, kidneys, heart, lungs, blood vessels and brain. It is an autoimmune disease—an illness that occurs when the body mistakenly detects its own tissue as foreign and attacks itself, and can be fatal in some severe cases. While people of all races can have the disease, African American women have a three-times higher number of new cases than white, non-Hispanic women. African American women tend to develop the disease at a younger age than white, non-Hispanic women and to develop more serious and life-threatening complications. It is also



Sources:
Food and Drug Administration (FDA) and American College of Rheumatology

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more common in women of Hispanic, Asian and Native American descent.

The underlying cause of lupus is not fully known, and there are many types of the disease. The most common form, called systemic lupus erythematosus, commonly causes mouth sores, rash, fatigue, joint pain and swelling, as well as affecting the kidneys.

Lupus also is a chronic disease. "With treatment, the disease may quiet down, but it also may relapse eventually. Although it may be controlled with medications, once you get it, you will always have it," explains Sarah Yim, M.D., a rheumatologist at the Food and Drug Administration (FDA). A person with lupus will have good periods and bad periods, she says, and symptoms can range from mild or moderate to severe.

Who is Affected?

Estimates vary on the number of lupus sufferers in the United States, ranging from approximately 300,000 to 1.5 million people. According to the American College of Rheumatology, ten times more women than men have lupus, and the disease often starts between the ages of 15 and 44.

What makes lupus so hard to diagnose? A lot of people can be called lupus sufferers but can all have different things wrong with their immune systems, Yim says. And many of the symptoms that can occur in someone with lupus are non-specific and can also occur in other diseases, making it hard to nail down the diagnosis.

Jonca Bull, M.D., director of FDA's Office of Minority Health, says there is still an enormous need for better therapeutics, and that scientists may be on the cusp of more refined therapies that bring symptoms under control and bring about remission of the diseases that are associated with susceptibility to lupus or play a role in its development. FDA's Office of Women's Health has funded several studies related to lupus and other autoimmune diseases in recent years.

Targeting Therapies

Treatment of lupus depends on the part of the body being affected by the disease, and how serious the problem. FDA approved the first drug to treat lupus, aspirin, in 1948 and later approved corticosteroids, such as prednisone, which suppress the immune system and reduce inflammation. In 1955, the agency approved the antimalarial drug Plaquenil (hydroxychloroquine) which helps to relieve some lupus symptoms such as fatigue, rashes, joint pain or mouth sores.

Part of what makes lupus research such a challenge is that the precise problem with the immune system is so different among patients, Yim says. New research is trying to zero in on what the best targets might be.

"Technologies have been developed in recent years that can make our medicines more targeted to address the specific molecule or molecules in the immune system that may be causing the problem," Yim says. "Older medicines tend to suppress the whole immune system, which works, but it's a little bit like shooting a fly with a cannonball, and can be associated with many undesirable side effects."

FDA approved Benlysta—the first targeted therapy for lupus—in 2011. Benlysta is delivered directly into a vein. It is designed to target a protein called B-lymphocyte stimulator, which may reduce the impact of abnormal cells thought to be a factor in the development of lupus.

Yim says that Benlysta doesn't work for everyone, and not enough research has been done yet to know if it will work in people with very severe lupus. But it works well for lupus patients with skin and joint involvement, she says.

Advances in the understanding and treatment of lupus over the last several decades have resulted in people with the disease living longer.

Despite these advances, however, there remain many people with lupus who need additional treatment options. FDA remains committed to working with researchers and drug developers to help make new treatments a reality. FDA

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